Approvals & Updates

December 2023

New Drug Approvals

PharMerica®

Augtyro (repotrectinib)

Indication: ROS1-positive non-small cell lung cancer (NSCLC)

Mechanism of action: Kinase inhibitor

Dosage form(s): Capsule

Comments: Augtyro is FDA-approved to treat adult patients with locally advanced or metastatic ROS1-positive NSCLC. The recommended dosage is 160mg once daily for 14 days, followed by 160mg twice daily, without regard to food. Warnings and precautions associated with Augtyro include central nervous system (CNS) effects (i.e., dizziness, ataxia, cognitive impairment), interstitial lung disease/pneumonitis, hepatotoxicity, myalgia with creatine phosphokinase (CPK) elevation, hyperuricemia, skeletal fractures, and embryo-fetal toxicity. Additional considerations include monitoring serum CPK levels, liver function tests, and serum uric acid levels. The most common adverse effects (≥20%) include dizziness, dysgeusia, peripheral neuropathy, constipation, dyspnea, ataxia, fatigue, cognitive disorders, and muscle weakness. Patients experiencing CNS effects should be monitored and Augtyro withheld or discontinued based on severity. Augtyro has reported drug interactions and concomitant use should be avoided with strong and moderate CYP3A inhibitors and inducers, P-gp inhibitors, some CYP3A substrates, and hormonal contraceptives.

Defencath (taurolidine and heparin)

Indication: Reduce catheter-related bloodstream infections (CRBSI)

Mechanism of Action: Combination thiadiazinane antimicrobial and anti-coagulant

Dosage form(s): Catheter lock solution

Comments: Defencath is a combination thiadiazinane antimicrobial and anti-coagulant catheter lock solution FDA-approved for adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC) to reduce the incidence of CRBSI. Defencath is for instillation into CVC's only and not systemic use. Recommended administration includes the use of a 3mL or 5mL single dose vial and Defencath is instilled into each catheter lumen once HD has concluded. The volume of Defencath used is dependent upon the catheter lumens volume. It is important to note that Defencath is required to be aspirated from the catheter and discarded prior to the next HD session. Known contraindications to Defencath include heparin-induced thrombocytopenia (HIT), hypersensitivity to taurolidine, heparin, citrate excipient, or pork products. Warnings and precautions associated with Defencath include HIT and drug hypersensitivity reactions. The most common adverse effects (≥2%) include hemodialysis catheter malfunction, hemorrhage/bleeding, nausea, vomiting, dizziness, musculoskeletal chest pain, and thrombocytopenia.

Fruzaqla (fruquintinib)

Indication: Metastatic colorectal cancer (mCRC)

Mechanism of Action: Kinase inhibitor

Dosage form(s): Capsule

Comments: Fruzaqla is a kinase inhibitor FDA-approved to treat mCRC in adults previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and an anti-EGFR therapy if RAS wild-type and medically appropriate. Fruzaqla 5mg should be administered by mouth once daily for the first 21 days of each 28-day cycle, without regard to food. Warnings and precautions associated with Fruzaqla include hypertension, hemorrhagic events, infections, gastrointestinal perforation, hepatotoxicity, proteinuria, palmer-plantar erythrodysesthesia, posterior reversible encephalopathy syndrome (PRES), impaired wound healing, arterial thromboembolic events, allergic reactions to FD%C Yellow No. 5 and No.6, and embryo-fetal toxicity. Additional considerations include monitoring for urine protein, bleeding, signs and symptoms of infection, and liver laboratory tests. Discontinuation of Fruzaqla is recommended in patients who develop nephrotic syndrome, PRES, arterial thromboembolism, GI perforation or fistula, and hypertension or hepatotoxicity (dependent upon severity). Do not initiate Fruzaqla in patients with an active infection. The most common adverse effects (≥ 20%) include hypertension, palmar-plantar erythrodysesthesia, proteinuria, dysphonia, abdominal pain, diarrhea, and asthma.

Ogsiveo (nirogacestat)

Indication: Desmoid tumors

Mechanism of Action: Gamma secretase inhibitor

Dosage form(s): Tablet

Comments: Ogsiveo is FDA-approved to treat progressing desmoid tumors in adult patients who require systemic treatment. The current recommended dosage is 150mg twice daily until disease progression or unacceptable toxicity. Warnings and precautions associated with Ogsiveo include diarrhea, ovarian toxicity, hepatotoxicity, non-melanoma skin cancers, electrolyte abnormalities, and embryo-fetal toxicity. The most common adverse effects (≥ 15%) include diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection, and dyspnea. Abnormal laboratory values include decreased phosphate and potassium, and increased urine glucose, urine protein, AST, and ALT. Additional considerations include monitoring for elevated AST and ALT, and decreased phosphate and potassium levels. Ogsiveo has reported drug interactions with strong CYP3A inhibitors, CYP3A inducers, and gastric acid reducing agents; therefore, concomitant use should be avoided.

Truqap (capivasertib)

Indication: Breast cancer

Mechanism of Action: Kinase Inhibitor

Dosage form(s): Tablet

Comments: Truqap, in combination with fulvestrant, is FDA-approved to treat HR-positive, HER2-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKTI/PTEN-alterations in adults following progression on at least one endocrine-based regimen or recurrence within 12 months of completing adjuvant therapy. The recommended dosage of Truqap is 400mg by mouth twice daily for 4 days followed by 3 days off, and can be administered without regard to food. Truqap is contraindicated in patients with severe hypersensitivity to the active ingredient or any component. Warnings and precautions associated with Truqap include hyperglycemia, diarrhea, cutaneous adverse reactions, and embryo-fetal toxicity. The most common adverse effects (≥ 20%) include diarrhea, cutaneous adverse effects, increased random and fasting glucose levels, increased triglycerides, decreased lymphocytes, leukocytes, neutrophiles, and hemoglobin, nausea, fatigue, vomiting, and stomatitis. Additional considerations for patients taking Truqap include monitoring blood glucose levels and for signs and symptoms of cutaneous adverse reactions. Drug interactions reported with Truqap include strong and moderate CYP3A inhibitors or inducers. Additionally, concomitant use should be avoided with strong CYP3A inhibitors and strong or moderate CYP3A inducers.

Recently Approved Drug Combinations, Dosage Forms/Strengths, Indications, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Alvaiz (Eltrombopag choline)	Persistent or chronic immune thrombocytopenia in patients ≥ 6 years with an insufficient response to corticosteroids, immunoglobulins, or splenectomy; thrombocytopenia in adults with hepatitis C; severe aplastic anemia in adults with insufficient response to immunosuppressive therapy	Thrombopoietin receptor agonist	Oral tablet	New salt form
Voquezna (Vonoprazan)	Healing all grades of erosive esophagitis; maintain healing of all grades of erosive esophagitis; relieve heartburn associated with erosive esophagitis; helicobacter pylori when used in combination	Potassium-competitive acid blocker	Oral tablet	New indication
Zepbound (Tirzepatide)	Chronic weight management in adults	Glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist	Subcutaneous injection	New indication

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